Final Program Review

Birmingham's Gulf War Veterans' Illness Demonstration Clinic

1. RESPONSIVENESS TO INITIAL PROPOSAL

a. What is the expected number of patients in the Demonstration Project and in the comparison group? Is the VA medical center Gulf War population large enough to give adequate sample size to meet study goals?
Answer: The Birmingham VA Medical Center's Primary Care Clinic alone saw 525 Gulf War veterans over the 12 month period immediately preceding the grant application. Also, there were 393 patients that visited the Special Emphasis Clinic (which was later to be converted into the Demonstration Clinic) between June 1997 and June 1998. These numbers helped form the basis for the expected number of patients in the Demonstration Project and in the comparison group and were sufficient to yield a sample size large enough to meet study goals.

b. Is a method for valid measurement of the study subject's health care utilization outlined?
Answer: Yes, the subject's health care utilization was assessed using costs of treatment under each clinic settings as captured by the Decision Support System (DSS) at the Birmingham VA Medical Center. Data was transferred to Excel for review and final analysis was performed using statistical analysis. Costs were grouped by clinic and summed per patient.

c. Are assessment measures utilized that can quantitatively or qualitatively demonstrate study outcomes?
Answer: Yes, assessment measures were used to determine symptoms, conditions, and feelings as they relate to Post-Traumatic Stress Disorder, fibromyalgia, depression, and anxiety. The questionnaires used in this study have been validated and are useful in the diagnosis of these disorders and therefore serve as measures of general and disease-specific functional status.

d. Are patient satisfaction and functional status determined using VA's national customer satisfaction survey form "1998 About Your VA Clinic Visits" and the SF-36 (modified for veterans) respectively? (Note: Satisfaction and functional status measurements were to be made for each participant before the onset of the Demonstration Project, after one year, and at the end of the two year project.)
Answer: Yes, patient satisfaction was determined using VA's national customer satisfaction survey form "1998 About Your VA Clinic Visits," and patient functional status (a measure of general health) was determined using the Health Assessment Project -VA Health Updates 36 (or SF 36), i.e. the Medical Outcomes Study Short Form 36 adapted to the VA (see Appendix A). These assessments were made for each participant before the onset of the Demonstration Project and during the second year of the two year project.

e. Have compliance requirements for staff experience, and expertise in clinical research, been reviewed?
Answer: Yes, staff experience and expertise in clinical research have been reviewed. Since there have been no substantial changes in staff members' levels of experience and expertise

that would impact on the outcomes of this clinical research over the course of this project, the compliance requirements have been met.

2. SCIENTIFIC MERIT

a. Has the health status of comparison or control patients not receiving services in the Demonstration Project been reviewed?
Answer: Yes, the health status of the each population has been reviewed and statistically compared.

b. Is any statistical power that has been generated thus far adequate to meet study goals?
Answer: Yes. For the small to medium effect size differences that were originally hypothesized in the study proposal, the power of this study (0.89) was sufficient to meet study goals at the 0.05 significance level.

c. Has the principle of good clinical study design been satisfied, and can a valid conclusion can be drawn upon project completion?
Answer: Yes, the principle of good clinical study design has been satisfied and valid conclusions can be drawn from the completed data.

3. RELEVANCE TO GULF WAR VETERANS' HEALTH

a. Do preliminary results contribute to the scientific body of knowledge in the areas of: 1) testing new approaches to health care delivery; and 2) improving the treatment satisfaction of Gulf War veterans suffering from undiagnosed and ill-defined illnesses, or disability?
Answer: Yes. The results presented in the Detail Summary Sheet contribute to the scientific body of knowledge in the area of testing new approaches to deliver health care to Gulf War veterans. One of the new approaches tested in this Demonstration Project was provision of the services of a nurse case manager which was shown to be an effective new application. These data also add to the body of scientific knowledge with regards to improving treatment satisfaction of Gulf War veterans, especially in those who continue to suffer from undiagnosed illnesses.

4. INNOVATION

a. Have any innovative or unique approaches to treatment been developed, or changes been undertaken, since the Demonstration Project was initiated?
Answer: No.

Report Date: August 30, 2000

DETAIL SUMMARY SHEET

TITLE: Birmingham's Gulf War Veterans' Illness Demonstration Clinic

KEYWORDS: Primary Care Clinics, Gulf War Special Emphasis Program Clinic, Demonstration Clinic, clinic-based support services, Case Manager, Gulf War veterans, patient satisfaction, functional outcomes, health care utilization, health care costs

PRINCIPAL INVESTIGATOR: Michael P. Everson, Ph.D.
CO-INVESTIGATOR(s): Warren D. Blackburn, M.D.

VA SITE: Birmingham, Alabama (521) **STATUS: X Ongoing** / **Complete**

APPROVAL DATE: August 7, 1998
REVIEW DATE:

FUNDING: Current FY: $ 117,900 **Total: $ 476,900**

STUDY OBJECTIVE:

The two specific objectives for this proposal were to determine whether:

i) Special Emphasis Clinics with a Case Manager provide greater patient satisfaction and better functional outcomes than Primary Care Clinics, and

ii) a Special Emphasis Clinic can be improved to provide even greater patient satisfaction and better functional outcomes by development of a Demonstration Clinic through the implementation of positive changes in operating procedures currently provided by Special Emphasis Clinics by the addition of support services (psychologist, social worker, benefits counselor, pharmacist, and chaplain) to these clinics.

The overall objective of this project is to determine the healthcare effectiveness of these three clinic settings by determining if there are differences in: 1) patient satisfaction, 2) patient functional status, 3) cost of care and resource utilization, and 4) knowledge about Gulf War Veterans' Illnesses.

TECHNICAL APPROACH:

The following items were changed or clarified during this project since the last annual report:

1) the time point for the second and subsequent mail outs to Gulf War veterans (T1) was shifted from T1=11-13 months to T1 + T2=13-22 months due to the protracted response by veterans to the initial mail out and the poor response to the T1 + T2 mail out;

2) questionnaires were to be administered at T1 and T2 to randomly selected veterans, however, this was changed to include all veterans seen in the clinics over the first time period due to poor response. Thus, the second and third mail outs were to all those who participated in the Demonstration Clinic and to all those who came to one of the four Primary Care Clinics during the initial time period (T0). This could have had the effect of making the groups longitudinal and complete (as opposed to random), however, poor subject participation and consequent participation bias dampened this effort; and

3) those veterans who came through the Demonstration Clinic and didn't respond via mail to our request for study participation were contacted by phone when possible to offer them participation in the T1 + T2 sampling.

Background information related to conclusions:

One of the goals of this study was to attempt to increase customer satisfaction in Gulf War veterans visiting our Gulf War clinic. For comparative purposes of our Demonstration Clinic with other outpatient clinics throughout the country, the following information is provided as a basis for comparison:

VA's GULF WAR VETERAN SATISFACTION SURVEY

(Letter: 5.3; abstracted form the VA Health Care: Better Integration of Services Could Improve Gulf War Veterans' Care [Letter Report, 08/19/98, GAO/HEHS-98-197]):

VA's National Customer Feedback Center implemented a survey in 1997 to over 41,000 Gulf War veterans who had received care in a VA outpatient facility during fiscal years 1992 through 1997. Forty percent of the veterans surveyed responded. The survey found that Gulf War era veterans are not satisfied with the continuity and overall coordination of the care they received. The VA survey also showed that Gulf War veterans, as a group, are generally more dissatisfied with VA care than VA's general outpatient population that responded to a similar satisfaction survey at an earlier date. For example, while 62 percent of the general patient population responded that the overall quality of care provided by VA was excellent or very good, only 38 percent of Gulf War veterans responded in this way. Twenty-nine percent of the Gulf War veterans rated the quality of VA's care as fair to poor. Furthermore, while 54 percent of the general

population reported they would definitely choose to come to the same VA facility again, only 24 percent of Gulf War veterans reported that they would.

The Demonstration Clinic was established at the Birmingham VA Medical Center in an attempt to improve the satisfaction of Gulf War veterans with the care they receive at the Birmingham Gulf War clinic. To initiate the study regarding this new clinic, letters containing an invitation to participate in the study and an informed consent form were mailed to Gulf War veterans at time zero (T0). Approximately 1400 letters were mailed to Gulf War veterans at the beginning of the study. During the first few months of this study, a small number of these were returned as undeliverable without forwarding address information. Approximately 20 additional letters were returned that had forwarding addresses but were not delivered because the forwarding time had expired. Because of poor mail response, 681 follow-up telephone calls were made to these veterans to determine if they had received the letters. Approximately 260 letters were re-mailed to veterans following requests from veterans during the follow-up conversation to receive another letter because the first letter had been lost, discarded, or not received. These baseline activities yielded 317 signed informed consent forms from which 304 of these Gulf War veterans have received a structured 90-minute telephone interview. Attempts to contact the remaining 13 were unsuccessful. The respondents were 161 patients from Primary Care Clinics and 143 patients from the Special Emphasis Clinic.

Original estimates suggested that 250 patients would be seen in the Demonstration Clinic in the first year (approximately 21 new patients/month) based on a census of 393 patients visiting the Special Emphasis Clinic between June 1997 and June 1998 (33 new patients/month). However, over the course of the entire study period, we have had only 200 Gulf War veterans visit the Demonstration Clinic (20 new patients/month). These 200 patients had 408 visits to the Demonstration Clinic (approximately 2 visits per patient between 091198 and 063099). The chief diagnoses listed for these patients in descending order of prevalence were joint pain, benign hypertension, prolonged post-traumatic stress, neurotic depression, chronic sinusitis, allergic rhinitis, late effect of war injury, multiple joint pain, anxiety state, dermatitis, and esophageal reflux.

Original estimates suggested that we would use 200 patients (38%) from Primary Care Clinic visits based on a census of 525 Gulf War patients visiting the Birmingham VA Primary Care Clinics over the 12 months prior to the grant submission (44 new patients/month). However, over the past 10 months, we have had only 408 Gulf War veterans visit the Primary Care Clinics (41 new patients/month) yielding only 161 respondents (39%) from Primary Care Clinics. Due to the shortened time frame, poor response rate, and lack of substantial differences in questionnaire answers for the T0 time point, the number of patients needed to demonstrate statistically significant differences was not met. Nonetheless, had there been a larger difference in patient questionnaire responses, the numbers would have been sufficient to document statistical differences. Because there was not a statistically significant difference between the Primary Care Clinics group and the Special Emphasis Clinic group, and as an aid for future statistical comparisons (i.e., T0 versus T1 + T2), the data for the Primary Care Clinic group and the Special Emphasis Clinic group were pooled, thus giving the study a larger n value for T0.

We initiated a second round of letter mailings to Gulf War veterans to assess the one-year follow-up to our initial baseline data. The poor and protracted response to this second mailing resulted in three more mailings with different cover letters in attempts to increase patient participation. The mailings that did not yield return responses were followed with repeated attempts by phone to establish contact with the individual patients. These efforts have represented a continuum of contact attempts to date and have yielded 137 Primary Care Clinic patients and 77 Demonstration Clinic patients for T1 + T2..

CONCLUSIONS:

1) The first study objective was accomplished and the data revealed that there was no statistically significant difference between the Special Emphasis Clinic and the Primary Care Clinics as they related to patient satisfaction and functional outcomes. The cost analysis comparing the Special Emphasis Clinic and the Primary Care Clinics originally indicated that the Special Emphasis Clinic was considerably more expensive than the cost for care in the Primary Care Clinics. Reexamination of these cost data indicated that the analyzed costs included in-patient as well as out-patient costs. This has been corrected in the final cost analysis of the Demonstration Clinic below.

2) The second study objective was accomplished and the data revealed that there were indeed statistically significant differences between the Demonstration Clinic and the previous Special Emphasis Clinic and the Primary Care Clinics as they related to patient satisfaction and functional outcomes. These statistical data confirm the personal comments from the veterans visiting the Demonstration Clinic who stated that they were appreciative of the VA's efforts and were more satisfied with the new Demonstration Clinic and its enhanced services than with the previous Special Emphasis Clinic. The statistical comparisons that follow support the anecdotal observation above.

Health and Behavioral Results From Gulf War Survey

Primary Care Clinics + Special Emphasis Clinic (termed Pri+SEC, n=303) versus Demonstration Clinic (termed Demo Clinic, n=77)

a. Using a patient satisfaction questionnaire (Customer Satisfaction Survey, dated February 20, 1998, provided by the VHA National Customer Feedback Center), Demo Clinic patients were more satisfied than Pri+SEC patients with:

-explanation of prescribed medications	p=0.001
-explanation of side effects	p=0.008
-provider courtesy	p=0.017
-staff accommodation for future visits	p=0.0104

b. Using the VA Health Assessment questionnaire (SF 36), the Pri+SEC group was in better health than the Demo Clinic group p=0.0001

Specific findings relative to the Demo Clinic group included:

-Pri+SEC were not limited as much by activity	p<=0.05

- Pri+SEC were in better emotional health p<=0.05
- Pri+SEC were less depressed as told by their doctor p=0.0001

In another area of questioning, the Demo Clinic patients also generally rated themselves in poorer health than Pri+SEC patients:
32% Demo Clinic vs. 12% Pri+SEC p=0.0002

d. Surprisingly, Pri+SEC group was less dissatisfied with C&P needs being met:
63% Pri+SEC not satisfied vs. 79% Demo Clinic not satisfied p=0.0013

e. Using the Beck' anxiety scale:
Demo Clinic had higher levels of anxiety overall p=0.0001

f. Using the Fibromyalgia scale:
within past year, no difference between Pri+SEC and Demo Clinic, but
over their lifetime, Pri+SEC had a higher score p=0.0001

g. Using the Beck Depression Inventory:
Demo Clinic had higher levels of depression (18.4) vs. Pri+SEC (12.8) p=0.0001

h. Using the Mississippi Post-Traumatic Stress Disorder questionnaire, there was not much difference between the groups. However, Demo Clinic patients considered themselves as having it "tougher to go on with life", having more nightmares, having more trouble concentrating, and considered themselves less "easy going" than did the Pri+SEC group (all these comparisons were at $p < 0.05$).

3) Continuing with regard to patient satisfaction, the statistician ranked the scored values of <0.20 as being "highly satisfactory," where a low score (closer to zero) represented greater satisfaction than a high score (closer to one). Using this as a measure of satisfaction, Demonstration Clinic patient data (T1 + T2) were compared to the pooled T0 data discussed above.

The results indicate that the Demonstration Clinic group found it easier to get appointments (score=0.107; p=0.028), experienced less waiting time (0.121; 0.007), and had greater satisfaction after visit (0.152; 0.022). Scores close to this level of satisfaction were indicated by these patients for satisfaction with provider (0.227; 0.061) and should not be ignored. Other satisfaction parameters did not achieve statistically significant differences.

4) With regard to cost analysis, the total Demonstration Clinic (out-patient) data were compared with the last 9 months of Primary Care Clinics (out-patient) data to correct for the previous reported finding. Using DSS, the cost per visit (mean ± standard deviation) for the Primary Care Clinics (n=17,433) was \$106.65 ± \$74.58, and the cost per visit for the Demonstration Clinic (n=67) was \$102.69 ± \$59.88. Although not statistically significantly different, the Demonstration Clinic costs represented an approximate 4% cost savings for the medical center.

5) The overall conclusion is that as the study progressed during the period of approximately 8-10 years after Gulf War military deployment, the patients lost interest in attending the special Gulf War Demonstration Clinic even though increased efforts had been made to enhance the care they received. The dwindling number of study participants resulted in an apparent participation bias. That is, the patients that continued to visit the clinic and participate in the study still had undiagnosed illnesses and were in generally poorer health than those that had quit visiting the clinic. This was made evident by the statistical comparison of the T0 group to the T1 + T2 group.

A perplexing outcome of this study was that the Demonstration Clinic patients were less satisfied with their C&P needs being met than the T0 patients. The Clinic was specifically designed to have a Benefits Officer physically present in the Clinic to help the Gulf War veterans work their way through the large volume of forms and documentation required to successfully file for compensation benefits. Although this negative result appeared paradoxical at first (because the Benefits Officer should have made it easier for the veterans to receive rapid compensation adjudication), this finding was in keeping with the current policy that veterans with undiagnosed illnesses do not receive compensation. Therefore, the undiagnosed veterans are still in poor health, are still looking for answers to their problems, and are still dissatisfied with their lack of compensation.

EXPORTABILITY TO OTHER VA FACILITIES:

The overall success of this project is supported by increased customer satisfaction in multiple areas of the clinical care provided. This project also further defined the Gulf War veterans who continue to seek answers for their symptoms and complaints at VA clinics. The nurse case manager and ancillary support services coalesced as a supportive team to help these veterans using compassionate and understanding care. Nonetheless, there continue to be barriers to their total satisfaction and healing, some of which may be able to be removed, others that may not.

It is felt that the effectiveness of such a Demonstration Clinic intervention could be much more pronounced immediately after a war or at other post-deployment times. In this regard, the Birmingham VA personnel are continuing to utilize the Demonstration Clinic approach as they apply for further funding in war-related illnesses especially as they are related to post-deployment servicemembers and veterans.

The exportability of this information to other VA facilities would be in the form of increased numbers of Benefits Officers who can make regular clinic visits (as opposed to having the veterans find the Benefits Officer's office in a corner of a hospital) and the increased use of nurse case management to orchestrate the fulfillment of veteran needs following future military deployments. Taken together, the application of these measures could significantly impact on the stress that veterans feel once they enter a VA for care.

End of Enclosure 2

FY 00 CONTINUING REVIEW OF RESEARCH

INSTRUCTIONS: Please answer the following questions and sign at the bottom of the page. Give an explanation for all negative responses.

YES	**NO**	
__X___	_.___	1. Research files are being maintained by the principal investigator.
__X__	_.___	2. These files are ready to be inspected as part of the continuing periodic review process as required by VHA and other federal regulations.
__X__	_.___	3. If human use, subject participation or risk has not been influenced by new developments or literature.
__X__	_.___	4. If human use, the current risk/benefit ratio is about the same (or lower) as when the study was first approved.
__X__	_.___	5. If human use, I have reviewed the consent form during this report period to ensure its appropriateness (give date of review:_5/31/00). The consent form has been revised and updated, if required, to meet HUC/IRB guidelines.

_____ _____

Signature Date

PROVIDE A COPY OF THE CURRENT CONSENT FORM AND, IF REQUIRED, A COPY OF THE REVISED/UPDATED VERSION.

--see attached, non-paginated consent form --

End of Enclosure 3

Report Date **August 31, 2000**

FY00 LIST OF PUBLICATIONS

DIRECTIONS: List publications (P), presentations (Pr), and abstracts (A) resulting from this study. Please provide complete citations. IF THERE HAVE BEEN NONE, PLEASE SO STATE,

(P) None

(Pr) Everson, M.P. Birmingham's Gulf War Veterans' Illness Demonstration Clinic: Design and Function. Conference on Federally Sponsored Gulf War Veterans' Illnesses Research, Pentagon City, VA, 1999.

(A) Baker DG, Crisfield J, Engel CC Jr, Epstein LJ, Everson MP, Hunt SC. Emerging Clinical Efforts to Assist Gulf War Veterans with Chronic Multisymptom Illnesses. 1999 Conference on Federally Sponsored Gulf War Veterans' Illnesses Research. Pentagon City, VA. June 25, 1999.

End of Enclosure 4